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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,618	03/02/2004	Sherman Fong	GNE-1192-2C1	4005

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,618	FONG ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 30 September 2008, have been entered in full. Claims 1-11 are canceled. Claim 12 was amended. Claim 12 is pending and under examination.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The basis for this rejection is set forth at pages 3-13 of the previous Office Action (31 March 2008).

Applicant states claim 12 now recites a method of enhancing the infiltration of immune cells in a mammal, comprising administering to the mammal an effective amount of Bolekine polypeptide, wherein the immune cells are mononuclear cells, eosinophils, or polymorphonuclear neutrophils (PMNs). Applicant states that the claim is drawn to enhancing the infiltration of immune cells for which the specification provides actual experimental data, thus its scope is fully supported by the disclosure of the present application. Applicant argues that in addressing the alleged limitations of the Miles assay, Applicants refer to the expert Declaration of Dr. Fong (of record). Applicant states that the fact, statements and conclusions have not been effectively

rebutted by the Examiner. Applicant maintains that while the Baggliolini reference referred to in the Declaration, may not teach that "any one chemokine can enhance the infiltration of all immune cells (in any type of disease or condition) and/or alleviate any type of infection in a mammal", it is irrelevant in view of the current claim scope.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that as a result of the cancellation of claim 14, the Examiner's comment on the scope of infections to be treated, in accordance with the present invention, no longer apply. This argument and the argument regarding the Baggliolini reference are not found persuasive because claim 12 still encompasses any condition/diseases wherein "enhancing the infiltration of immune cells in a mammal" would be beneficial. The ability to stimulate lymphocyte Bolekine proliferation in the MLR assay (an *in vitro* model for screening immunosuppressive agents) and cause inflammation at the site of injection in a vascular permeability assay (an *in vitro* model for preliminary screens of potential proinflammatory molecules) is not tantamount to an effective method of enhancing the infiltration of immune cells (eosinophils, mononuclear cells, polymorphonuclear and/or neutrophils) in a mammal (for any type of disease or condition). The data from the instant assays does not teach what specific setting the claimed invention would predictably function. Lastly, the Examiner thoroughly addressed the shortcomings of the Miles assay. Please see the previous Office Actions (3/31/08, pages 4-5 and 1/27/06, pages 5-6 and pages 9-10).

Applicant asserts, that based on its primary structure, Bolekine has been identified as a novel chemokine. Applicant argues that based on general knowledge in

the art that several chemokines are known to activate immune cells, one of ordinary skill would accept the data disclosed in the present application as valid, and would be able to practice the invention within the full scope of pending claim 12 without undue experimentation. Applicant, reiterates the Examiner's comment that Applicants have not provided a sequence alignment, which demonstrates that the instant Bolekine polypeptide (SEQ ID NO: 2) is indeed CXCL14/BRAK. Applicant argues that the attached entry from NCBI Genbank clearly establishes that CXCL14, BRAK and Bolekine are synonyms for the same chemokine. Applicant argues that the sequence of Bolekine is accessible under the same accession number (NP 004878) as that of BRAK and CXCL14.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant provides a GeneBank printout. But as was stated in the previous office action, Applicant has not provided a sequence alignment, which demonstrates that **the instant Bolekine polypeptide (SEQ ID NO:2) is 100% identical to CXCL14/BRAK (i.e. a sequence alignment between instant SEQ ID NO:2 and CXCL14/BRAK).** However, even if the Bolekine protein (SEQ ID NO:2) were found to be a novel chemokine and was 100% identical to CXCL14/BRAK, it would not be enabled for the breadth of the instant claim. The references of record fail to teach the administration of CXCL14/BRAK to enhance the infiltration of eosinophils, mononuclear cells, polymorphonuclear and/or neutrophils in a mammal for a specific disease/condition.

Applicant argues that pending claim 12 is not directed to the enhancement of "any type" of immune cell or the treatment of "any type" of disease or infection. Accordingly, the scope of claim 12 is entirely commensurate with the specific teaching provided in the present application, when read by one skilled in the art, taking into account the general knowledge in the art at the time the present invention was made. Applicant argues that it is noted that absolute certainty is not required for patentability, and even extensive experimentation is permissible, as long as it is routine in nature.

Applicant's arguments have been fully considered but are not found persuasive. The specification fails to teach how to use the instant invention (i.e. test of enablement). The Examiner understands that there are many conditions which benefit from an enhanced infiltration of immune cells but the data from Examples 10 and 11 are not applicable to the instant claims. As was stated above, the instant specification fails to teach a specific disease/condition, wherein infiltration of immune cells can be enhanced upon administration of the Bolekine protein. It would be highly unpredictable to correlate the data taught in the specification with effectively administering the Bolekine protein to enhance the infiltration of immune cells in a mammal for any condition/disease. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. M. D./
Examiner, Art Unit 1647
1/16/09

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647